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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,397

04/08/2004

Jerome B. Zeldis

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EXAMINER

SUTTON, DARRYL C

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

12/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/820,397	<b>Applicant(s)</b> ZELDIS ET AL.	
	<b>Examiner</b> DARRYL C. SUTTON	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-49,51-55 and 74-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-49,51-55 and 74-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's arguments filed 09/12/2008 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 102***

Claims 47-49 were rejected under 35 U.S.C. 102(b) as being anticipated by Midha et al. (US 6,217,904).

The rejection is maintained.

Applicant argues that the claims have been amended to a composition comprising as the active ingredient, d-threo methylphenidate substantially free of l-threo and erythro methylphenidates, while Midha et al. require that the d-threo methylphenidate be co-administered with a second CNS stimulant in order to achieve a therapeutic effect. Applicant also argues that Midha et al. teach that using pure d-threo methylphenidate is ineffective for individuals that do not respond, or respond inadequately to methylphenidate therapy.

The Examiner disagrees. The claims are drawn to a method comprising administration of a composition "comprising" as the active ingredient, d-threo methylphenidate. The use of the limitation "comprising" renders the claim open-ended

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and contemplates other components which may act as an active ingredient and/or other steps in the method. Furthermore, the Examiner disagrees with Applicant's interpretation of Midha et al., column 3, lines 18-23. Midha et al. disclose that methylphenidate can be used in the treating mood elevation of patients suffering from cancer, i.e. patients suffering from mood disorders respond to methylphenidate, and therefore, the interpretation discussed by Applicant would mean that pure d-threo methylphenidate would be effective in producing mood elevation in cancer patients (column 10, line 67-column 11, lines 1-4).

### ***Claim Rejections - 35 USC § 103***

Claims 47-49, 51-55 and 74-78 were rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers et al. (J. Clinical Oncol., 1998).

The rejection is maintained.

Applicant argues that Meyers et al. teach that the treatment is inexpensive and relatively free of side effects, and therefore, one in the art would not be motivated to remove the l-thro isomer of methylphenidate since removal is expensive.

The Examiner disagrees. Meyers et al. teach that the treatment is "relatively" free of side effects, not that there are no side effects of the treatment. At the time of the invention it was known in the art that treatment with racemic methylphenidate caused side effects due to the l-threo isomer. The side effects include insomnia, euphoria, development of tolerance to the drug, and potential for abuse (see Midha et al. US

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6,217,904, column 3, lines 4-10). The physiological function of each of the isomers of methylphenidate are responsible for the therapeutic effects as well as the undesirable side effects of racemic methylphenidate, therefore one would be motivated to remove the l-threo isomer in order to provide an effective treatment without the side effects.

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612